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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,463	10/14/2004	Yuval Simha Landschaft	RO0908US (#905668)	9282

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,463	LANDSCHAFT, YUVAL SIMHA	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/04, 3/21/06 and 2/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGFMENT TO PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE CLAIMS AND APPLICATION

1. This application is filed under 35 U.S.C. 371 on 10/14/04 having a filing date of 06/21/03 of PCT/IB03/03467. Acknowledgement is made of Applicant's claim for priority based on German Application No. 102286809 having a filing date of 06/27/02. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The preliminary amendment, information disclosure statement (IDS) and Form PTO-1449 filed 10/14/04 and supplemental IDS and Form PTO-1449 filed, 03/21/05 and 02/02/06, respectively are acknowledged, entered and considered. In view of Applicant's request claims 1-15 have been amended and claim 16 has been added. Claims 1-16 are now pending in the application.

OBJECTION TO THE CLAIM

2. Claim 14 is objected in the recitation the acronym "TTS". Use of the full terminology at least in the first occurrence would obviate this objection.

Claims 11-13 and claim 16 are objected in the recitation "organic sulfur" (claim 11) and "organic sulphur" (claim 16). There is inconsistency between the terms "organic sulfur" and "organic sulphur". Appropriate correction is required.

CLAIM REJECTION-35 U.S.C. § 102(a) & (e)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6, 11 and 13-15 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by Kirby et al (U.S. Patent No. 6,444,234).

The reference of Kirby et al ('234 patent) discloses a composition for transdermal administration of at least one therapeutically active compound (polypeptide) or nutrient (Vitamins), said composition comprising one item selected from the group consisting of at least one therapeutically active compound such as antibiotics drugs and at least on nutrient and a non-oily emulsion (cholesterol), wherein the polypeptide has a molecular weight of 500 D and higher (overlaps with the range of up to 7000 kDa of claim 5) and further comprising an organic sulfur compound (methylsulfonylmethane), wherein the composition for transdermal administration of active substance which is nutrients and/or

medications are useful as a cream, gel, lotion, ointment and patch (See, e.g. cols 1, 5-11, 15, 31 and 32) as directed to claims 1, 2, 4-6, 11 and 13-15.

Therefore, the prior art clearly discloses a composition for transdermal administration comprising therapeutically active compound such as polypeptide and antibiotic drugs, nutrients such as vitamins and non-oily emulsion such as cholesterol and further comprising organic sulfur compounds such as methylsulfonylmethane (MSM). Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed product/composition as taught by the reference anticipates claims 1, 2, 4-6, 11 and 13-15 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirby et al (U.S. Patent No. 6,444,234) taken with Yamamoto et al (U.S. patent No. 5,759,445), Guo et al (Drug Deliv. Vol. 7, No. 2, pp. 113-116, 2000) and Thorand et al (Southeast Asian J. Trop. Med. Public Health, Vol. 24, No. 4, pp. 624-630, 1993).

The primary reference of Kirby et al ('234 patent) as discussed above discloses a composition for transdermal administration of at least one therapeutically active compound (polypeptide) or nutrient (Vitamins), said composition comprising one item selected from the group consisting of at least one therapeutically active compound such as antibiotics drugs and at least on nutrient and a non-oily emulsion (cholesterol), wherein the polypeptide has a molecular weight of 500 D and higher (overlaps with the range of up to 7000 kDa of claim 5) and further comprising an organic sulfur compound (methylsulfonylmethane), wherein the composition for transdermal administration of active substance which is nutrients and/or medications are useful as a cream, gel, lotion, ointment and patch (See, e.g. cols 1, 5-11, 15, 31 and 32) as directed to claims 1, 2, 4-6, 11 and 13-15.

The primary reference of '234 patent differs from claims 1-16 in not teaching the use of non-oily emulsion which is a mixture of lecithin, bile salt and cholesterol with the specific ratio and amount disclosed in the claims, and the use of a nutrient which is an ionic compound and the ionic compound is a metal ion. However, the secondary reference of Guo et al discloses a study of transdermal delivery of insulin (therapeutically active compound and/or peptide) in mice by using lecithin vesicles as a carrier. The study was undertaken to characterize the preparation of flexible lecithin vesicles containing insulin and to assess the enhancing effect of these flexible vesicles on the transdermal delivery of a hydrophilic proteins or polypeptides. The reference concludes by stating flexible vesicles may become a promising carrier for transdermal delivery of hydrophilic polypeptides (See e.g. Abstract and Discussion). Further, the

secondary reference of Yamamoto et al ('445 patent) discloses an aqueous dispersed solution, which comprises the steps of evaporating an organic solvent from a mixture prepared by adding cholesterol, lecithin, a surfactant and a neutral lipid, and/or a cholesterol ester in the organic solvent in a specific range of the concentration ratio. The preferred weight ratio of the sum of the cholesterol and cholesterol ester to the lecithin is from 1:1 to 1:2, a weight ratio of the neutral lipid to the lecithin is from 1:10 to 1:5, and a concentration of the lecithin is not more than 1,000 mg/dl when the lecithin is finally dispersed in a water or buffer (See e.g. Summary of the Invention and claim 4) as directed to claims 7-10. Thus, utilizing the mixtures of non-oily emulsion of lecithin, bile salt and cholesterol is a choice procedure as pointed out by the secondary reference of '445 patent, and as such use of non-oily emulsion which is a mixture of lecithin, bile salt and cholesterol is deemed to be obvious to one of ordinary skill in the art because the skilled artisan would reasonably have expected that use of non-oily emulsion such as lecithin would have resulted as a promising carrier for transdermal delivery of hydrophilic polypeptides as taught by the secondary reference of Guo et al. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to employ a composition for transdermal administration of the primary reference because such features are known or suggested in the art, as seen in the secondary reference, and including such features (i.e., use of non-oily emulsion which is a mixture of lecithin, bile salt and cholesterol) into a composition for transdermal administration of at least one therapeutically active compound (polypeptide) or nutrient (Vitamins), said composition comprising one item selected from the group consisting of

at least one therapeutically active compound such as antibiotics drugs and at least on nutrient and a non-oily emulsion (cholesterol), wherein the polypeptide has a molecular weight of 500 D and higher and further comprising an organic sulfur compound (methylsulfonylmethane), wherein the composition for transdermal administration of active substance which is nutrients and/or medications are useful as a cream, gel, lotion, ointment and patch.

With respect to the limitations of a nutrient, which is an ionic compound and the ionic compound, is a metal ion, the secondary reference of Thorand et al demonstrates that the administration of iron (metal ion) supplement is an effective intervention in treating anemia caused by iron deficiency. Thus, the reference shows the administration of at least one therapeutically active compound and said at least one nutrient is an ionic compound and wherein the ionic compound is a metal ion (i.e., iron as a nutrient), and as such meet the limitation of claim 2 and 3.

Thus, in view of the above, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the primary reference's teaching of a composition for transdermal administration into secondary references teachings because the secondary reference teach the use of non-oily emulsion which is a mixture of lecithin, bile salt and cholesterol, and the use of a nutrient which is an ionic compound and the ionic compound is a metal ion. Because use of non-oily emulsions and a nutrient ionic compound which is a metal ion are known and suggested in the art as seen the secondary references, and including such features into the composition of the primary reference which teaches a composition for transdermal administration of at least one

therapeutically active compound (polypeptide) or nutrient (Vitamins), said composition comprising one item selected from the group consisting of at least one therapeutically active compound such as antibiotics drugs and at least on nutrient and a non-oily emulsion (cholesterol), wherein the polypeptide has a molecular weight of 500 D and higher and further comprising an organic sulfur compound (methylsulfonylmethane), wherein the composition for transdermal administration of active substance which is nutrients and/or medications are useful as a cream, gel, lotion, ointment and patch would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, in view of the above and in view of the combined teachings of the prior art; one of ordinary skill in the art would have been motivated at the time the invention was made to use the already known composition for transdermal administration comprising therapeutically active compound such as polypeptides and antibiotic drugs, nutrients such as vitamins, ionic compounds which are metal ions and non-oily emulsions such as lecithin, bile salt and cholesterol and further comprising organic sulfur compounds such as methylsulfonylmethane (MSM), wherein the composition for transdermal administration of active substance which is nutrients and/or medications are useful as a cream, gel, lotion, ointment and patch, absent of sufficient factual evidence or unexpected results to the contrary.

Although, the prior art does not teach the specific amounts of lecithin, bile salts, cholesterol and organic sulfur, and the ratio of by weight of lecithin, bile salts and cholesterol as claimed, however, the ranges claimed and cited by the prior art overlaps,

and as such the selection of the appropriate specific amounts of lecithin, bile salts, cholesterol and organic sulfur, and the ratio of by weight of lecithin, bile salts and cholesterol is conventional and within the ordinary skill of the art to which this invention pertains. Therefore, the claimed specific amounts of lecithin, bile salt, cholesterol and organic sulfur, and the ratio of by weight of lecithin, bile salts and cholesterol, which fall within the scope of the prior art would have been *prima facie* obvious from said prior art disclosure to a person of ordinary skill in the art at the time the invention was made because in the absence of sufficient objective factual evidence or unexpected results to the contrary, Applicant's claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art, *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON WEBER
SUPERVISORY PATENT EXAMINER

/Mohamed/AAM
January 7, 2007